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| 09/779,596 | 02/09/2001 | Jean-Richard Neeser | 88265-406 | 6562 |

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| EXAMINER |
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KERR, KATHLEEN M

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 07/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,596

Applicant(s)

NEESER ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 10, mailed on December 18, 2002), Applicants filed an amendment and response received on April 22, 2003 (Paper No. 14). Said amendment cancelled Claims 2, 5, and 11-22, amended Claims 1, 23, and 28, and added new Claim 29. Thus, Claims 1, 3, 4, 6-10, and 23-29 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application requests the benefit of priority for the foreign application 98202707.0 filed in Europe on December 8, 1998. However, the instant application does not comply with the rules set out in 35 U.S.C. § 119 (a)-(d) since a certified copy of the original foreign application has not been filed with the Office. Applicants noted in response that a certified copy was sent to the Office on February 28, 2003; however, the copy received was not an official certified copy with ribbons. Copies are not acceptable. Moreover, the introduction of pages 3-4 after-the-fact is also not acceptable. A complete, ribboned, certified copy from the European patent office is required to perfect the claim to foreign priority.

In the instant Office action, the priority date used is that of the parent application, PCT/EP99/05473 filed on July 26, 1999, claimed as a continuation in the transmittal sheet.

Withdrawn - Objections to the Specification

3. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment.
4. Previous objection to the specification for improper terms on page 1 is withdrawn by virtue of Applicants' amendment.
5. Previous objection to the specification for the following informalities and/or confusions is withdrawn:
 - a) On page 5, the term "renneted milk" has been reconsidered by the Examiner to be a term of art.
 - b) On page 5, the terms "quark" and "coffee cream" has been reconsidered by the Examiner to be a term of art.
 - c) On page 15, near the middle, the term "Belliker", referring to a media, is clear considering the previous description in Example 1 as noted by Applicants. No amendment is required.

Maintained – Objections to the Specification

6. Previous objection to the specification for having improper margins (see M.P.E.P. § 608.01) is maintained. Applicants included substitute pages of the specification along with their response; however, no direction for its entry has been received. Moreover, the substitute specification is improper (see 37 C.F.R. § 1.125). A proper substitute specification is required.
7. Previous objection to the specification for the following informalities and/or confusions is maintained:
 - a) On page 5, second full paragraph, "X17390", "X14490", and "X53657" are unclear references. Applicants argue that these are GenBank references numbers. If this is

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the case, then they must be described as such at least upon their *first occurrence* in the specification for clarity. Correction is required.

- b) On page 14, near the bottom, the term “FUM medium” is noted but the term is unclear. This term is also found in the middle of page 15. Definition, as found in the art, is required to clarify the specification. Applicants argue that the term is dully understood in the field; the Examiner, as an ordinarily skilled artisan in the field, disagrees. Since the Examiner can find no reference to the abbreviation in the art (i.e., a journal article defining the term), Applicants must supply it since FUM is clearly not a common term of art.

Withdrawn - Objections to the Claims

8. Previous objection to Claim 2 for an apparent typographical error is withdrawn by virtue of Applicants’ cancellation of said claim. Moreover, the integration of the corrected pH range is found in Claim 1.

9. Previous objection to Claim 5 for depending from rejected claims is withdrawn by virtue of Applicants’ cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

10. Previous rejection of Claims 1-4, 6-10, and 23-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “low acidifying” is withdrawn by virtue of Applicants’ amendment. However, the maintained rejection below for the term “about” is related to the clarity of the instant term.

11. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the reference to gene numbers is withdrawn. By Applicants’ arguments, these are GenBank numbers and are, thus, clear.

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12. Previous rejection of Claims 9 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “milk derivative” is withdrawn by virtue of the Examiner’s reconsideration.

13. Previous rejection of Claims 10 and 26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “renneted milk” is withdrawn by virtue of the Examiner’s reconsideration.

14. Previous rejection of Claims 23-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “to provide a pH of at least 5.5” is withdrawn by virtue of Applicants’ amendment to Claim 1, from which Claim 23 depends. The pH limits of the parent claim are about 5.5-7, thus, the cited pH of at least about 5.5 is clearly a lower limit in Claim 23.

15. Previous rejection of Claims 27-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms “oil soluble antioxidant”, “abrasive”, “quark”, and “coffee cream” is withdrawn by virtue of the Examiner’s reconsideration.

New or Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

16. Previous rejection of Claims 1, 3, 6-10, and 23-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “lactic bacteria that are not part of the resident microflora or the mouth” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that “it is well known as to which bacteria are and are not resident in the mouth”. Applicants provide no references to attest this fact. The Examiner, being an ordinarily skilled artisan, maintains that the metes and bounds of the term are

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unclear since no particular reference can be found in the specification and/or the art. Moreover, the Examiner notes that the instant claim reads on the mouths of all animals, not just humans. Additionally, must the bacteria only be not a part of the resident microflora of the subject to which the bacteria are administered (i.e., if treating a human with bacteria found only in the mouth of dogs, is this within the scope of the claims?)? With all these concepts in mind, the metes and bounds of the term are unclear. Clarification is required.

17. Previous rejection Claims 2 and 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “about” with respect to a pH range or a temperature, respectively, is amended. Presently, Claims 1, 3-10, and 23-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “about” due to its unclear metes and bounds. With respect to the pH range, the term “about” also affects the clarity of the term “low acidifying” since it is used to define “low”. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that the term “about” is “explicitly endorsed by the M.P.E.P.”. However, the M.P.E.P. § does not define the clarity of terms in a vacuum; all terms in claims must be assessed on a case-by-case basis. In the instant case, no direction can be found in the specification as to how varied the pH or temperature can be and still meet the limitations of the claims. More specifically, **NO REFERENCE** to particular pH’s is found in the Examples whatsoever. Thus, no direction of *any kind* is given for the varying of the pH range while remaining within the scope of the claims. Thus, one of skill in the art could not ascertain the scope of the term with any certainty from the specification as originally filed.

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18. Previous rejection of Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “of dairy origin” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that “the term ‘of dairy origin’ clearly means that the lactic bacteria are derived [from] a dairy product, which in turn required no definition as a common word in everyday parlance.” The Examiner disagrees. The instant specification is replete with examples of recombinant DNA and strain technologies. Thus, in the field under which the instant application is filed, the term “dairy origin” requires clear definition. Must the lactic bacteria be naturally occurring? If not, how many alterations to a naturally occurring dairy lactic acid bacteria strain can be made before the strain is considered “of different origin”? Clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

19. Previous rejection of Claim 28 under 35 U.S.C. § 132 and 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants’ amendment to that which was originally filed as “sweet salad dressing”.

New or Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

20. Previous rejection of Claims 1, 3, 4, 6-10, and 23-28 under 35 U.S.C. 112, first paragraph, written description, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive. Applicants argue that the Lilly case is not applicable because said case is drawn to DNA claims while the instant claims are drawn to methods of using recombinant bacteria, to which genetic guidelines are not applicable. The Examiner disagrees. While the claims in Lilly are distinct from the instant subject matter, the concept of “requiring a

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precise definition, such as by structure, formula, or chemical name” is not. To practice the claimed methods, the genus of low acidifying lactic bacteria is required as a reagent and, thus, must be described. To fully describe a genus of genetic material, including recombinant bacteria, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. In the instant case, no correlation of the structure of the bacterial strains and their function is provided. The bacteria in the examples of the specification were identified by a screening process. Applicants have described the five strains in Claim 5, which were borne out of the screening process. No structural commonalities between these strains are defined. The specification does not describe a representative number of species in such a broad genus, except by functional characteristics, because, using only the five described species, one of skill in the art could not reasonably predict the structure of other species encompassed by the claimed genus.

Applicants also argue that the names of the lactic bacteria in Claim 4 are sufficient. This is not the case since the invention is drawn to using particular strains of the bacteria noted in Claim 4. Applicants further argue that the property of being low acidifying is clearly taught. While the function is taught, the structure responsible for this function (i.e., is correlated to) is wholly without explanation. Again, the claimed function was found by means of a screening process and no further characterization of the identified bacterial strains was performed so that

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one of skill in the art could identify other members of the genus of lactic bacteria used in the claims.

Applicants argue that the instant inventors have not invented a bacterium, but a composition. The Examiner fails to see the distinction since the bacteria, identified by screening, are required for the composition used in the claimed methods.

21. Previous rejection of Claim 7 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using lactic bacteria modified to contain one of the three genes in Claim 8, does not reasonably provide enablement for methods using lactic bacteria modified in other ways to cause improved adhesion and/or to be less acidifying than the resident microflora is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the Examiner has the burden to present a *prima facie* case of a lack of enablement; the Examiner did so in the assessment of the claims using the Wands factors in the previous Office action. Applicants also argue that the specification provides guidance and specific examples of the modification necessary for Claim 7; the Examiner disagrees. As previously noted, "the instant specification presents no guidance of working examples for the production of genetically modified lactic bacteria that have improved adhesion and/or are less acidifying than the resident microflora other than the use of three particular genes as noted in Claim 8. In the absence of any guidance, the quantity of experimentation would be significant. The state of the prior art contains extensive work on mouth microflora, but little is known about genetically modified bacteria that can take up residence in the mouth. Most striking is the unpredictability of the genetic modifications

required to meet the limitation of the instant claim to the full extent of its scope.” For all these reasons, the above rejection is maintained.

Maintained - Claim Rejections - 35 U.S.C. § 102

22. Previous rejection of Claims 1, 3-4, 6, 9, and 28 under 35 U.S.C. § 102(b) as being anticipated by Madinier (WO 92/14475) is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that Madinier does not teach bacteria within the pH limitations of the claims. Since the pH limitations of the claims are unclear as noted above in a rejection under 35 U.S.C. § 112, second paragraph, this argument is not persuasive. Applicants also argue that the bacteria of Madinier do not adhere to the teeth surface. However, the instant claims are drawn to use of bacteria “capable of adhering”, which is not a definite limitation. Madinier does not teach anything that prohibits the bacteria from adhering, thus, the bacteria are “capable” of adhering.

23. Previous rejection of Claims 1, 3-4, 6, and 28 under 35 U.S.C. § 102(b) as being anticipated by Busscher *et al.* is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that Busscher *et al.* do not teach bacteria within the pH limitations of the claims. Since the pH limitations of the claims are unclear as noted above in a rejection under 35 U.S.C. § 112, second paragraph, this argument is not persuasive. Applicants also argue that the bacteria of Busscher *et al.* do not adhere to the teeth surface. However, the instant claims are drawn to use of bacteria “capable of adhering”, which is not a definite limitation. Busscher *et al.* do not teach anything that prohibits the bacteria from adhering, thus, the bacteria are “capable” of adhering. Moreover, the bacteria of Busscher *et al.*

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are capable of preventing attachment of cariogenic bacteria strains even though the teaching is directly related to yeast colonization (i.e., nothing prohibits this function).

Summary of Pending Issues

24. The following is a summary of the issues pending in the instant application:

- a) Official priority documents must be received of the claim to priority cancelled.
- b) The specification stands objected to for having improper margins and require a substitute specification.
- c) The specification stands objected to for informalities and/or confusions relating to GenBank numbers and FUM media.
- d) Claims 1, 3, 6-10, and 23-28 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "lactic bacteria that are not part of the resident microflora or the mouth".
- e) Claims 1, 3-10, and 23-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "about" due to its unclear metes and bounds.
- f) Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "of dairy origin".
- g) Claims 1, 3, 4, 6-10, and 23-28 stand rejected under 35 U.S.C. 112, first paragraph, written description.
- h) Claim 7 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- i) Claims 1, 3-4, 6, 9, and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Madinier (WO 92/14475).
- j) Claims 1, 3-4, 6, and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Busscher *et al.*

Conclusion

25. Claim 29 is allowed in the Office action; claims 1, 3, 4, 6-10, and 23-28 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPUACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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KMK
July 6, 2003